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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,309	10/26/2001	Rodney A. Welch	096429-9117	2988

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,309	Applicant(s) WELCH ET AL.	
	Examiner Tekchand Saidha	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-11 is/are rejected.
- 7) ☐ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

1. Applicant's amendment and response filed March 25 2004, is acknowledged.

2. **Claims withdrawn :**

Claims 12-21 were previously [Office Action mailed 10.22.2003] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in the above cited response to the restriction requirement.

3. Claims 1-11 are pending and under consideration in this examination.

4. Applicant's arguments filed as per the amendment cited above have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

5. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

6. Rejection of claim 5 under 35 U.S.C. 112, first paragraph [enablement], is withdrawn in view of the amendment to the claim.

7. ***35 U.S.C. § 112, first paragraph (Written Description)***

Claims 1-3 & 6-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-3 & 6-11 encompass specific fragments of SEQ ID NO : 2 with no associated function.

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The specification, however, only provides a single representative species of the genus comprising SEQ ID NO : 2, having the desired ability to bind and cleave C1-esterase inhibitor. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species to other species of specific fragments of SEQ ID NO : 2, where such fragments of specific amino acid residues (for example, 230-630; claims 1-3 & 9-11) or fragments of 17, 25 or 40 consecutive amino acid residues (claims 6-8) have the desired ability to bind and cleave C1-esterase inhibitor, and for which no predictability of structure/activity is apparent. Given this lack of additional representative species, such as the modifications in order to create a variant, fragment or derivative of the Formula and still have some activity and/or utility, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Therefore, the written description requirement is not satisfied.

Applicants' Arguments :

Applicants pointing to instant specification (at page 6, paragraph 29) argue that the peptide fragments of SEQ ID NO : 2 could function as antigens in developing antibodies; and larger fragments as claimed in claims 1-3 could reasonably be expected to retain activity and both the larger (claims 1-3) and smaller (claims 6-11) fragments would be useful for raising StcE-specific antibodies.

Applicant's arguments is considered, however not found persuasive, because claims are not drawn to fragments having the ability to bind and to cleave C1 esterase

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or immunogenic fragments of SEQ ID NO : 2 for raising StcE-specific antibodies – therefore no function is associated with the claims. The rejection is therefore maintained.

8. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 & 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Makino et al. [DNA Research 5 : 1-9, (1998)] or Burland et al. [Nucleic acid Research, 26 : 4196-4204, (1998), see 1449 (ref : AJ)]. Makino et al. or Burland et al. disclose a polypeptide sequence (Accession No. T42131; T00210) that is 100% identical to SEQ ID NO : 2, or comprises the polypeptide residues or fragments of claims 1-3 & 6-11. The reference anticipates the claims (see the sequence search alignment, and the cited reference of Makino et al., provided previously).

9. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunder (Accession No. Q9ZAL1, May 1, 1999, see 1449 (Ref : AS)). Brunder teaches a polypeptide sequence, Accession No. Q9ZAL1), wherein 275 consecutive amino acid residue match with Applicant's SEQ ID NO : 2. This polypeptide sequence comprises any fragments having 17, 25 or 40 consecutive amino acids of claims 6-8. The

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reference anticipates the claims (see the sequence search alignment between Q9ZAL1 and SEQ ID NO : 2 (residue 24-886), provided previously.

Applicants' Arguments :

Applicants discussing the rejection under 35 U.S.C. 102(b) as anticipated by the prior art works of Makino et al. or Burland et al. or Brunder in items 8 and 9 above, argue that their polypeptide is an isolated StcE polypeptide, discovered by correlating the loss of an observed phenotype, as compared to the hypothetical protein sequences cited in the 102 rejections.

Irrespective of the way the polypeptide was discovered, the claims are directed to any polypeptide or fragments thereof without any assigned function such as that disclosed in the specification [having the ability to bind and to cleave C1 esterase], no difference is seen between Applicants' polypeptide and that of the prior art. The rejections in items 8 and 9 are therefore maintained.

10. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants argue that it is not necessary to rewrite claim 4 as an independent claim because claim 1, from which claim 4 depends, is also patentable.

Having considered Applicants' arguments, and as indicated above, claim 1 is not yet found to be patentable. The objection is therefore maintained. This is explained above in the rejections as well as is obvious from the arguments presented. Combining the subject matters of claim 1 and 4, may be allowable.

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11. ***Allowable Subject matter***

Claims drawn to 'sequence(s) of SEQ ID NO : 2 having the ability to bind and cleave C1-esterase inhibitor' – which recite both structure and function, have been found unobvious over the cited prior art.

12. Claim 5 is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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